JUN 2 1 2004

K040700

510(k) Summary

General Information

Classification	Class II, Percutaneous Catheter per 21 CFR § 870.1250
Trade Name	Concentric Retriever
Submitter	Concentric Medical, Inc. 1380 Shorebird Way Mountain View, CA 94043 650-938-2100
Contact	Kevin F. MacDonald Vice President, Clinical and Regulatory Affairs

Intended Use

The Concentric Retriever is indicated for use in the retrieval of foreign bodies misplaced during interventional radiological procedures in the neuro, peripheral and coronary vascular systems.

Predicate Devices

Concentric Retriever K003410, K030476
Manufactured by Concentric Medical, Inc.

Device Description

The Concentric Retriever consists of a Nitinol tapered wire with a helical shaped distal tip. A radiopaque distal coil facilitates fluoroscopic visualization.

Materials

All materials used in the manufacture of the modified Concentric Retriever are suitable for this use and have been used in numerous previously cleared products.

Testing Summary

The modified Concentric Retriever was tested in a similar manner as the predicate Concentric Retriever (K003410, K030476). All components, subassemblies, and/or full devices met the required specifications for the completed tests. The modified Concentric Retriever was designed under the Concentric Quality System which is in compliance with 21CFR§820.30.

Summary of Substantial Equivalence

The modified Concentric Retriever is equivalent to the predicate product, the Concentric Retriever. The indications for use, function, methods of manufacturing, and materials used are substantially equivalent. Concentric Medical, Inc. believes the Concentric Retriever is substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 1 2004

Mr. Kevin F. MacDonald
Vice President, Clinical and Regulatory Affairs
Concentric Medical, Inc.
1380 Shorebird Way
Mountain View, CA 94043

Re: K040700
Trade/Device Name: Percutaneous Introducer
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: DQY
Dated: June 11, 2004
Received: June 14, 2004

Dear Mr. MacDonald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K040700

510(k) Number (if known):	This application
Device Name:	Concentric Retriever
Indications for Use:	The Concentric Retriever is indicated for use in the retrieval of foreign bodies misplaced during interventional radiological procedures in the neuro, peripheral and coronary vascular systems.

Prescription Use __X__ OR Over-The-Counter Use____

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040700